

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 19734-502	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US99/07360	International filing date (day/month/year) 01/04/1999	Priority date (day/month/year) 01/04/1998
International Patent Classification (IPC) or national classification and IPC A61K35/74		
Applicant GANEDEN BIOTECH, INC. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  28/10/1999	Date of completion of this report  26.05.2000
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Cattell, James  Telephone No. +49 89 2399 8468



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/07360

## I. Basis of the report

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

### Description, pages:

1-32 as originally filed

### Claims, No.:

1-76 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 1-30(IA) , 54-76.

because:

- ☒ the said international application, or the said claims Nos. 1-30(IA) relate to the following subject matter which does not require an international preliminary examination (*specify*):

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/07360

**see s parate sheet**

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 54-76 are so unclear that no meaningful opinion could be formed (*specify*):

**see separate sheet**

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims 1-53
	No: Claims
Inventive step (IS)	Yes: Claims
	No: Claims 1-53
Industrial applicability (IA)	Yes: Claims 31-53
	No: Claims

**2. Citations and explanations**

**see separate sheet**

III.

- 1). Claims 1-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
- 2). Claims 54 to 76 are so unclear under Rule 6 PCT that no opinion can be formed. It is not clear whether a "system" refers to a method or product.

V.

- 3). Document D1 (Mohan et al 1990 Indian.J.Med. 92;431-2) discloses that *L.sporogenes* can reduce cholesterol levels. Document D2 (EP-A-0,307,158) discloses on page 3 lines 5 to 10 disclose that fructooligosaccharides can reduce cholesterol. It is self evident that "cholesterol reducing agents" reduce cholesterol.

Hence the claims consist of constructs of three known cholesterol reducing agents to reduce cholesterol. All acting in a known ingredients are acting in a known manner. No inventive merit can be seen on such as use under Article 33(3) PCT.

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NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

26.05.2000

Applicant's or agent's file reference

19734-502 PRC-06-1

## IMPORTANT NOTIFICATION

International application No.  
PCT/US99/07360International filing date (day/month/year)  
01/04/1999Priority date (day/month/year)  
01/04/1998

Applicant

GANEDEN BIOTECH, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



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Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
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Senkel, H

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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>19734-502</b>	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
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International Patent Classification (IPC) or national classification and IPC <b>A61K35/74</b>		
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Date of submission of the demand  <b>28/10/1999</b>	Date of completion of this report  <b>26.05.2000</b>
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  <b>Cattell, James</b>  Telephone No. +49 89 2399 8468



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US99/07360

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**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/US99/07360

see separate sheet

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see separate sheet

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	No: Claims
Inventive step (IS)	Yes: Claims
	No: Claims 1-53
Industrial applicability (IA)	Yes: Claims 31-53
	No: Claims

**2. Citations and explanations**

see separate sheet



III.

- 1). Claims 1-30 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
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- 3). Document D1 (Mohan et al 1990 Indian.J.Med. 92;431-2) discloses that *L.sporogenes* can reduce cholesterol levels. Document D2 (EP-A-0,307,158) discloses on page 3 lines 5 to 10 disclose that fructooligosaccharides can reduce cholesterol. It is self evident that "cholesterol reducing agents" reduce cholesterol.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61K 35/74 // (A61K 35/74, 38:04, 31:70) (A61K 35/74, 35:78, 31:70)</b>		A2	(11) International Publication Number: <b>WO 99/49877</b>
			(43) International Publication Date: 7 October 1999 (07.10.99)
(21) International Application Number: PCT/US99/07360		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 1 April 1999 (01.04.99)			
(30) Priority Data: 60/080,378 1 April 1998 (01.04.98) US			
(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/080,378 (CIP) Filed on 1 April 1998 (01.04.98)			
(71) Applicant (for all designated States except US): GANEDEN BIOTECH, INC. [US/US]; Suite 209, 5940 Pacific Mesa Court, San Diego, CA 92121 (US).			
(72) Inventors; and (75) Inventors/Applicants (for US only): FARMER, Sean [US/US]; 8738-6 Villa La Jolla Drive, La Jolla, CA 92037 (US). LEFKOWITZ, Andrew, R. [US/US]; Unit C, 8625 Via Mallorca, La Jolla, CA 92037 (US).		<b>Published</b> Without international search report and to be republished upon receipt of that report.	
(74) Agent: FITTING, Thomas; Suite 300, 12526 High Bluff Drive, San Diego, CA 92130 (US).			
(54) Title: METHODS FOR REDUCING CHOLESTEROL USING <i>BACILLUS COAGULANS</i> SPORES, SYSTEMS AND COMPOSITIONS			
(57) Abstract <p>The invention describes therapeutic compositions including a lactic acid-producing bacteria, such as isolated <i>Bacillus coagulans</i>, in combination with a bifidogenic oligosaccharides or other cholesterol-reducing agents for use in reducing LDL cholesterol and serum triglycerides. Also described are therapeutic methods using the compositions and systems containing the therapeutic compositions.</p>			

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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : <b>A61K 35/74 // (A61K 35/74, 38:04, 31:70) (A61K 35/74, 35:78, 31:70)</b>		<b>A3</b>	(11) International Publication Number: <b>WO 99/49877</b>
			(43) International Publication Date: 7 October 1999 (07.10.99)
<p>(21) International Application Number: PCT/US99/07360</p> <p>(22) International Filing Date: 1 April 1999 (01.04.99)</p> <p>(30) Priority Data: 60/080,378 1 April 1998 (01.04.98) US</p> <p>(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application US 60/080,378 (CIP) Filed on 1 April 1998 (01.04.98)</p> <p>(71) Applicant (for all designated States except US): GANEDEN BIOTECH, INC. [US/US]; Suite 209, 5940 Pacific Mesa Court, San Diego, CA 92121 (US).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): FARMER, Sean [US/US]; 8738-6 Villa La Jolla Drive, La Jolla, CA 92037 (US). LEFKOWITZ, Andrew, R. [US/US]; Unit C, 8625 Via Mallorca, La Jolla, CA 92037 (US).</p> <p>(74) Agent: FITTING, Thomas; Suite 300, 12526 High Bluff Drive, San Diego, CA 92130 (US).</p>			<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 16 December 1999 (16.12.99)</p>
(54) Title: METHODS FOR REDUCING CHOLESTEROL USING <i>BACILLUS COAGULANS</i> SPORES, SYSTEMS AND COMPOSITIONS			
(57) Abstract			
<p>The invention describes therapeutic compositions including a lactic acid-producing bacteria, such as isolated <i>Bacillus coagulans</i>, in combination with a bifidogenic oligosaccharides or other cholesterol-reducing agents for use in reducing LDL cholesterol and serum triglycerides. Also described are therapeutic methods using the compositions and systems containing the therapeutic compositions.</p>			

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# INTERNATIONAL SEARCH REPORT

Application No

PCT/US 99/07360

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K35/74 //(A61K35/74,38:04,31:70),(A61K35/74,35:78,31:70)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 011, no. 259 (C-441), 21 August 1987 (1987-08-21) & JP 62 061572 A (NIPPON OIL & FATS CO LTD; OTHERS: 01), 18 March 1987 (1987-03-18) abstract	1-76
A	EP 0 457 539 A (KUREHA KAGAKU KOGYO K.K.) 21 November 1991 (1991-11-21) page 2, line 28 - line 31 page 4, line 39 - line 48 page 5, line 9 - line 18; claims; examples 4,5,9	1-76

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

19 October 1999

Date of mailing of the international search report

02/11/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
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Fax: (+31-70) 340-3016

Authorized officer

Ryckebosch, A

## INTERNATIONAL SEARCH REPORT

Inventor Application No

PCT/US 99/07360

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	G. MOLIN ET AL.: "EFFECT OF FERMENTED OATMEAL SOUP ON THE CHOLESTEROL LEVEL AND THE LACTOBACILLUS COLONIZATION OF RAT INTESTINAL MUCOSA" ANTONIE VAN LEEUWENHOEK, vol. 61, no. 3, 1992, pages 167-173, XP002119334 AMSTERDAM, NL the whole document ----	1-76
A	J.C. MOHAN ET AL.: "PRELIMINARY OBSERVATIONS ON EFFECT OF LACTOBACILLUS SPOROGENES ON SERUM LIPID LEVELS IN HYPERCHOLESTEROLEMIC PATIENTS." THE INDIAN JOURNAL OF MEDICAL RESEARCH, vol. 92, 1990, pages 431-432, XP002119335 NEW DELHI cited in the application the whole document ----	1-76
A	EP 0 307 158 A (NIHON SHOKUHIN KAKO CO.) 15 March 1989 (1989-03-15) page 5, line 36 - line 42 ----	1-76
P,X	G. SCHAAFSMA ET AL.: "EFFECTS OF A MILK PRODUCT, FERMENTED BY LACTOBACILLUS ACIDOPHILUS AND WITH FRUCTO-OLIGOSACCHARIDES ADDED, ON BLOOD LIPIDS IN MALE VOLUNTEERS." EUROPEAN JOURNAL OF CLINICAL NUTRITION, vol. 52, no. 6, June 1998 (1998-06), pages 436-440, XP002119336 LONDON, GB page 439, right-hand column, paragraph 4 -----	1-18, 29-42, 53-65,76

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 07360

### Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
Remark: Although claims 1-30 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.



# INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No

PCT/US 99/07360

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 62061572 A	18-03-1987	NONE	
EP 457539 A	21-11-1991	JP 1942733 C	23-06-1995
		JP 4218501 A	10-08-1992
		JP 6078367 B	05-10-1994
		AU 625531 B	16-07-1992
		AU 7702291 A	28-11-1991
		CA 2042426 A,C	16-11-1991
		DE 69101080 D	10-03-1994
		DE 69101080 T	05-05-1994
		ES 2048560 T	16-03-1994
		KR 9404889 B	04-06-1994
		US 5308618 A	03-05-1994
EP 307158 A	15-03-1989	JP 1063389 A	09-03-1989
		JP 2806522 B	30-09-1998
		AT 109797 T	15-08-1994
		DE 3851022 D	15-09-1994
		DE 3851022 T	24-11-1994
		US 5334516 A	02-08-1994

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>GBI 0010P</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/US 99/ 07360</b>	International filing date (day/month/year) <b>01/04/1999</b>	(Earliest) Priority Date (day/month/year) <b>01/04/1998</b>
Applicant <b>GANEDEN BIOTECH, INC. et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.

---



None of the figures.

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
**Remark: Although claims 1-30 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.**
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

## INTERNATIONAL SEARCH REPORT

International Application No

T/US 99/07360

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	G. MOLIN ET AL.: "EFFECT OF FERMENTED OATMEAL SOUP ON THE CHOLESTEROL LEVEL AND THE LACTOBACILLUS COLONIZATION OF RAT INTESTINAL MUCOSA" ANTONIE VAN LEEUWENHOEK, vol. 61, no. 3, 1992, pages 167-173, XP002119334 AMSTERDAM, NL the whole document ---	1-76
A	J.C. MOHAN ET AL.: "PRELIMINARY OBSERVATIONS ON EFFECT OF LACTOBACILLUS SPOROGENES ON SERUM LIPID LEVELS IN HYPERCHOLESTEROLEMIC PATIENTS." THE INDIAN JOURNAL OF MEDICAL RESEARCH, vol. 92, 1990, pages 431-432, XP002119335 NEW DELHI cited in the application the whole document ---	1-76
A	EP 0 307 158 A (NIHON SHOKUHIN KAKO CO.) 15 March 1989 (1989-03-15) page 5, line 36 - line 42 ---	1-76
P, X	G. SCHAAFSMA ET AL.: "EFFECTS OF A MILK PRODUCT, FERMENTED BY LACTOBACILLUS ACIDOPHILUS AND WITH FRUCTO-OLIGOSACCHARIDES ADDED, ON BLOOD LIPIDS IN MALE VOLUNTEERS." EUROPEAN JOURNAL OF CLINICAL NUTRITION, vol. 52, no. 6, June 1998 (1998-06), pages 436-440, XP002119336 LONDON, GB page 439, right-hand column, paragraph 4 -----	1-18, 29-42, 53-65, 76

## INTERNATIONAL SEARCH REPORT

International Application No

T/US 99/07360

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K35/74 //(A61K35/74,38:04,31:70),(A61K35/74,35:78,31:70)

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 011, no. 259 (C-441), 21 August 1987 (1987-08-21) & JP 62 061572 A (NIPPON OIL & FATS CO LTD;OTHERS: 01), 18 March 1987 (1987-03-18) abstract ----	1-76
A	EP 0 457 539 A (KUREHA KAGAKU KOGYO K.K.) 21 November 1991 (1991-11-21) page 2, line 28 - line 31 page 4, line 39 - line 48 page 5, line 9 - line 18; claims; examples 4,5,9 ----- -/--	1-76



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

19 October 1999

Date of mailing of the international search report

02/11/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Ryckebosch, A

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/07360

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 62061572 A	18-03-1987	NONE	
EP 457539 A	21-11-1991	JP 1942733 C	23-06-1995
		JP 4218501 A	10-08-1992
		JP 6078367 B	05-10-1994
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EP 307158 A	15-03-1989	JP 1063389 A	09-03-1989
		JP 2806522 B	30-09-1998
		AT 109797 T	15-08-1994
		DE 3851022 D	15-09-1994
		DE 3851022 T	24-11-1994
		US 5334516 A	02-08-1994

## PCT INTERNATIONAL COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
 United States Patent and Trademark  
 Office  
 Box PCT  
 Washington, D.C. 20231  
 ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 13 December 1999 (13.12.99)	
<b>International application No.</b> PCT/US99/07360	<b>Applicant's or agent's file reference</b> GBI 0010P
<b>International filing date (day/month/year)</b> 01 April 1999 (01.04.99)	<b>Priority date (day/month/year)</b> 01 April 1998 (01.04.98)
<b>Applicant</b> FARMER, Sean et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

28 October 1999 (28.10.99)

☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	Authorized officer  Y. KUWAHARA  Telephone No.: (41-22) 338.83.38
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